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(54) Devices, systems and methods to fixate tissue within the regions of body, such as the pharyngeal conduit

(57) Devices, systems and methods develop pressure forces to fixate or brace tissue in targeted pharyngeal structures and individual anatomic components within the pharyngeal conduit.

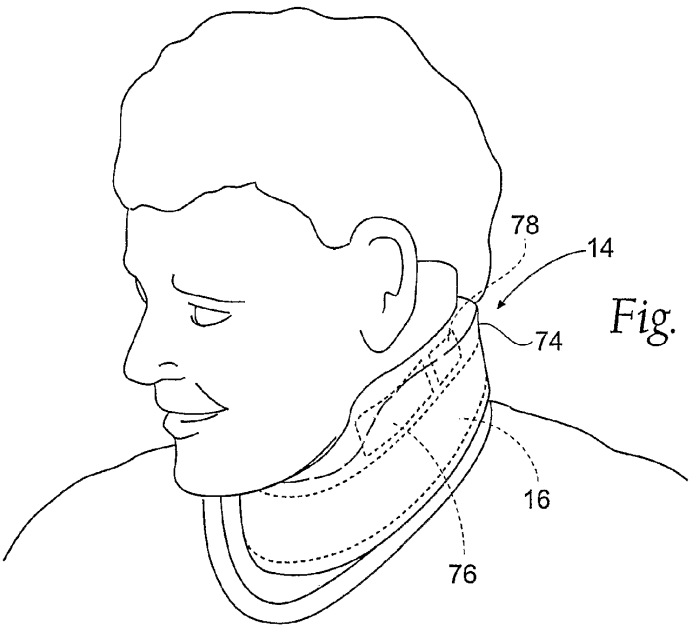

Fig. 3A

EP 2 433 593 A2

Description

Related Applications

[0001] This application claims the benefit of United States Patent Application Serial No. 10/656,861, filed September 6, 2003 and entitled "Magnetic Force Devices, Systems, and Methods for Resisting Tissue Collapse within the Pharyngeal Conduit"; United States Patent Application Serial No. 10/236,455, filed September 6, 2002 and entitled "Systems and Methods for Moving and/or Restraining Tissue in the Upper Respiratory System"; and United States Provisional Patent Application Serial No. 60/441,639, filed January 22, 2003 and entitled "Magnetic Splint Device and Method for the Treatment of Upper Airway Collapse in Obstructive Sleep Apnea"; and United States Provisional Patent Application Serial No. 60/456,164, filed March 20, 2003 and entitled "Device and Method for Treatment of Sleep Related Breathing Disorders Including Snoring and Sleep Apnea", which are each incorporated herein by reference.

Field of the Invention

[0002] The invention is directed to devices, systems, and methods for the treatment of sleep disordered breathing including obstructive sleep apnea.

Background of the Invention

I. The Characteristics of Sleep Apnea

[0003] First described in 1965, sleep apnea is a breathing disorder characterized by brief interruptions (10 seconds or more) of breathing during sleep. Sleep apnea is a common but serious, potentially life-threatening condition, affecting as many as 18 million Americans.

[0004] There are two types of sleep apnea: central and obstructive. Central sleep apnea, which is relatively rare, occurs when the brain fails to send the appropriate signal to the breathing muscles to initiate respirations, e.g., as a result of brain stem injury or damage. Mechanical ventilation is the only treatment available to ensure continued breathing.

[0005] Obstructive sleep apnea (OSA) is far more common. It is one of the several entities that make up the broader group of sleep disordered breathing (SDB). This group of disorders ranges from habitual snoring to OSA. Normally, the muscles of the upper part of the throat keep the airway open to permit air flow into the lungs. When the muscles of the upper airway relax and sag, the relaxed tissues may vibrate as air flows past the tissues during breathing, resulting in snoring. Snoring affects about half of men and 25 percent of women - most of whom are age 50 or older.

[0006] In more serious cases, the airway becomes blocked, making breathing labored and noisy, or even stopping it altogether. In a given night, the number of involuntary breathing pauses or "apneic events" can be quite frequent. These breathing pauses are almost always accompanied by snoring between apnea episodes, although not everyone who snores has OSA.

[0007] Lack of air intake into the lungs results in lower levels of oxygen and increased levels of carbon dioxide in the blood. The altered levels of oxygen and carbon dioxide alert the brain to resume breathing and cause arousal. The frequent interruptions of deep, restorative sleep often lead to early morning headaches, excessive daytime sleepiness, depression, irritability, and learning and memory difficulties.

[0008] The medical community has become aware of the increased incidence of heart attacks, hypertension and strokes in people with moderate or severe obstructive sleep apnea. It is estimated that up to 50 percent of sleep apnea patients have high blood pressure.

[0009] Upon an apneic event, the sleeping person is unable to continue normal respiratory function and the level of oxygen saturation in the blood is reduced. The brain will sense the condition and cause the sleeper to struggle and gasp for air. Breathing will then resume, often followed by continued apneic events. There are potentially damaging effects to the heart and blood vessels due to abrupt compensatory swings in blood pressure. Upon each event, the sleeping person will be partially aroused from sleep, resulting in a greatly reduced quality of sleep and associated daytime fatigue.

[0010] Although some apneic events are normal in all humans, the frequency of blockages will determine the seriousness of the disease and opportunity for health damage. When the incidence of blockage is frequent, corrective action should be taken.

II. Sleep and the Anatomy of the Upper Airway

[0011] As Figs. 1A and 1B show, the upper airway consists of a conduit that begins at the nasal valve, situated in the tip of the nose, and extends to the larynx. Although all tissue along this conduit is dynamic and responsive to the respiratory cycle, only the pharyngeal conduit structures--the tissues in the region of the airway that starts behind the nasal cavity and ends in its connections to the supraglottic larynx - - is totally collapsible. The pharyngeal structures and individual anatomic components within this region include the pharyngeal walls; the base of the tongue; the vallecula; the hyoid bone and its attachments; the soft palate with uvula, the palatine tonsils with associated pillar tissue; and the epiglottis.

[0012] The cross sectional area of the upper airway varies with the phases of the respiratory cycle. At the initiation of inspiration (Phase I), the airway begins to dilate and then to remain relatively constant through the remainder of inspiration (Phase II). At the onset of expiration (Phase III) the airway begins to enlarge, reaching maximum diameter and then diminishing in size so that at the end of expiration (Phase IV), it is at its narrowest, corresponding to the time when the upper airway dilator

muscles are least active, and positive intraluminal pressure is lowest. The upper airway, therefore, has the greatest potential for collapse and closure at end-expiration. Schwab RJ, Goldberg AN. Upper Airway Assessment: Radiographic and other Imaging Techniques. Otolaryngol Clin North Am 1998; 31: 931-968.

[0013] Sleep is characterized by a reduction in upper airway dilator muscle activity. For the individual with obstructive sleep apnea (OSA) and perhaps the other disorders which comprise much of the group of entities called obstructive sleep-disordered breathing (SDB), it is believed that this change in muscle function causes pharyngeal narrowing and collapse. Two possible etiologies for this phenomenon in OSA patients have been theorized. One is that these individuals reduce the airway dilator muscle tone more than non-apneics during sleep (the neural theory). The other is that all individuals experience the same reduction in dilator activity in sleep, but that the apneic has a pharynx that is structurally less stable (the anatomic theory). Both theories may in fact be contributors to OSA, but current studies seem to support that OSA patients have an intrinsically structurally narrowed and more collapsible pharynx. Isono S. Remmers J, Tanaka A Sho Y, Sato J, Nishino T. Anatomy of Pharynx in Patients with Obstructive Sleep Apnea and in Normal Subjects. J Appl Physiol 1997: 82: 1319-1326.

[0014] Although anatomic closure is often accentuated at specific sites, such as the velopharyngeal level [Isono, Ibid], studies of closing pressures [Isono, Ibid] supports dynamic fast MRI imaging that shows narrowing and collapse usually occurs along the entire length of the pharynx. Shellock FG, Schatz CJ, Julien P, Silverman JM, Steinberg F, Foo TKF, Hopp ML, Westbrook PR. Occlusion and Narrowing of the Pharyngal Airway in Obstructive Sleep Apnea: Evaluation by Ultrafast Spoiled GRASS MR Imaging. Am J of Roentgenology 1992: 158: 1019-1024.

III. Prior Treatment Modalities

[0015] To date, the only modality that addresses collapse along the entire upper airway is mechanical positive pressure breathing devices, such as continuous positive airway pressure (CPAP) machines. All other modalities, such as various surgical procedures and oral appliances, by their nature, address specific sectors of the airway (such as palate, tongue base and hyoid-vallecula levels), but leave portions of pharyngeal wall untreated. This may account for the considerably higher success rate of CPAP over surgery and appliances in controlling OSA. Although CPAP, which in essence acts as an airway splint for the respiratory cycle, is highly successful, it has some very significant shortcomings. It can be cumbersome to wear and travel with, difficult to accept on a social level, and not tolerated by many (for reasons such as claustrophobia, facial and nasal mask pressure sores, airway irritation). These factors have lead to a relatively poor long-term compliance rate. One study has shown that 65% of patients abandon their CPAP treatment in 6 months.

[0016] The need remains for simple, cost-effective devices, systems, and methods for reducing or preventing sleep disordered breathing events.

Summary of the Invention

[0017] An aspect of the invention provides devices, systems, and methods that brace or fixate tissue in targeted pharyngeal structures and/or individual anatomic components within the pharyngeal conduit by use of a pressure chamber, which is sized and configured to be located outside of the pharyngeal conduit and to hold a pressure that is less than atmospheric pressure. In one embodiment, the pressure chamber is sized and configured to hold a pressure that is less than a minimum pressure condition experienced in the pharyngeal conduit during a respiration cycle. The pressure chamber can be sized and configured, e.g., to be worn about a neck.

[0018] The devices, systems, and methods can be used to treat airway collapse and increased airway resistance associated with the entire spectrum of obstructive sleep-disordered breathing. The devices, systems, and methods can also be used to lend upper airway support in neurological associated dystonic disorders.

[0019] Other features and advantages of the invention shall be apparent based upon the accompanying description, drawings, and claims.

Description of the Drawings

[0020]

Figs. 1A and 1B are anatomic views of the upper airway in a human, showing certain pharyngeal structures and individual anatomic components within the pharyngeal conduit, Fig. 1A comprising a lateral view and Fig. 1B is a superior view taken generally along line 1B-1B in Fig. 1A.

Fig. 2 shows in a diagrammatic way a system that uses pressure to fixate or brace tissue along the pharyngeal conduit.

Figs. 3A and 3B show a pressure chamber system of a type shown in Fig. 2.

Detailed Description

[0021] Although the disclosure hereof is detailed and exact to enable those skilled in the art to practice the invention, the physical embodiments herein disclosed merely exemplify the invention, which may be embodied in other specific structure. While the preferred embodiment has been described, the details may be changed without departing from the invention, which is defined by the claims.

Pressure Chamber Systems

[0022] Fig. 2 shows in a diagrammatic way a pressure chamber system 14 that, in use, fixates or braces tissue in targeted pharyngeal structures and individual anatomic components within the pharyngeal conduit by altering the differential between internal pressure existing within the pharyngeal conduit (P1 in Fig. 2) and external pressure existing outside the pharyngeal conduit (P2 in Fig. 2). More particularly, the pressure chamber system 14 lowers, in a localized region surrounding all or a portion of the pharyngeal conduit, the external pressure to a pressure condition (P2) that is less than atmospheric pressure and desirably less than the minimum expected pharyngeal pressure (P1), which typically occurs during the inhalation phase of the respiratory cycle. The pressure chamber system 14 desirably creates in this localized region a pressure differential that impedes tissue collapse to maintain patency of the conduit. The purpose of the pressure chamber system 14 is to desirably nullify the vector sum of the extralumenal forces on the conduit, to make it decompressive. These forces are created by atmospheric pressure, gravity, contractive forces caused by upper airway muscle activity, and inward forces caused by subatmospheric luminal pressure generated during inhalation.

[0023] Like the force system 10, the pressure chamber system 14 can be used to treat airway collapse and increased airway resistance associated with the entire spectrum of obstructive sleep-disordered breathing. The pressure chamber system 14 can also be used to lend upper airway support in neurological associated dystonic disorders.

[0024] In one basic form, the pressure chamber system 14 comprises at least one external pressure chamber 16 (shown in Fig. 2), which is sized and configured to be worn by an individual, when desired, about a targeted tissue region or regions within the pharyngeal conduit. The targeted pharyngeal structures and individual anatomic components within this region can include the pharyngeal walls; the base of the tongue; the vallecula; the soft palate with uvula; the palatine tonsils with associated pillar tissue; and the epiglottis.

[0025] The pressure chamber 16 establishes a localized pressure condition (P2) about the targeted tissue region that is less than atmospheric pressure and desirably less than the minimum-expected pressure condition present in the pharyngeal conduit (P1). Exposed to a localized pressure differential that is more negative than ambient conditions, tissue along the pharyngeal conduit resists collapse when collapse is imminent, i.e., upon inhalation during sleep. The pressure chamber 16 can be removed during waking hours.

[0026] Illustrative embodiments of external pressure chamber systems 14 will now be described.

Illustrative Structures Useable with the Pressure Chamber System

[0027] Figs. 3A and 3B show an illustrative embodiment of a pressure chamber system 14. The system 14 includes a collar 74 that is sized and configured to be removably worn about the neck of an individual when the desired physiologic effect is desired, e. g., during sleep (as Fig. 3A shows).

[0028] The collar 74 carries a pressure-retaining chamber 16. When the collar 74 is worn, the chamber 16 encircles all or a portion of the pharyngeal conduit (see Fig. 3B). The chamber 16 may comprise an elastic material for comfort.

[0029] An air pump 76 has an inlet that communicates with the chamber 16 and an outlet that communicates with the ambient environment. The air pump 76 can be carried by the collar 74 (as shown), or it can be located remote from the collar, e.g., bedside, and coupled by tubing to the air chamber 16. The air pump 76 can comprise, e.g., a diaphragm pumping mechanism, or a reciprocating piston mechanism, or a centrifugal (turbine) air-moving mechanism.

[0030] The air pump 76 may be manually operated, or a power source 78 may drive the air pump 76. The power source 78 can be, e. g., an electric motor that can be plugged into a conventional electrical receptacle, or be battery- powered, or both (in which case the battery can be rechargeable). When driven, the air pump 76 draws air from the chamber 16, to establish within the chamber 16 a pressure condition that is less than atmospheric.

[0031] A regulator 80 may be coupled to govern operation of the air pump 76 to establish and maintain a desired sub-atmospheric pressure condition within the chamber 16. The desired pressure condition is selected to be less than atmospheric pressure and is desirably less the minimum pressure condition expected experienced in the pharyngeal conduit, which is typically encountered during the inhalation phase of the respiration cycle. The pressure selected desirably nullifies the vector sum of the extralumenal forces, which are created by the interaction of atmospheric pressure, gravity, the contractive forces within the tissue due to upper airway muscle activity, and the inward forces generated by subatmospheric luminal pressure generated during inhalation. It is believed that the pressure condition established within the chamber 16 should be at least -1 cm H_2O and desirable at least -10 cm H_2O. The pressure created by the system 14 desirably also takes into account different anatomical structural differences of individual airways.

[0032] The system 14 can also include some form of physiologic feedback control for the air pump. In this arrangement, the system includes a monitor or sensor 82 to sense fluctuations of pharyngeal pressure during the respiration cycle. When the pharyngeal pressure meets or exceeds a selected threshold minimum pressure, the monitor 82 sends a control signal to the pump 76, to activate the pump 76. The pump 76, when activated, oper-

ates to maintain a desired pressure condition within the chamber 16 while sensed pharyngeal pressure is below the threshold. The pump 76, when activated, could also operate to maintain a desired pressured differential between pressure in the chamber 16 and the sensed pharyngeal pressure while sensed pharyngeal pressure is below the threshold. Once pharyngeal pressure exceeds the threshold, the monitor 82 sends a control signal to deactivate the pump 76. In this way, the system 14 conditions tissue to resist collapse when respiratory conditions are most conducive to collapse, but otherwise does not affect the tissue morphology and/or motility and/or shape. The pressure chamber 16 can also serve to reduce tissue vibration and be used in the treatment of snoring.

[0033] Other forms of physiologic feedback control can be used. For example, airflow can be measured during the respiratory cycle, and/or the expansion/contraction of the chest can be monitored during the cycle. Chamber pressure can be varied to response to requirements dictated by the respiratory cycle.

[0034] The above-described embodiments of this invention are merely descriptive of its principles and are not to be limited. The scope of this invention instead shall be determined from the scope of the following claims, including their equivalents.

Claims

1. An apparatus to brace or fixate tissue in targeted pharyngeal structures and/or individual anatomic components within the pharyngeal conduit comprising a chamber sized and configured to be located outside of the pharyngeal conduit and to hold a pressure that is less than atmospheric pressure.

2. An apparatus according to claim 1, wherein the chamber is sized and configured to hold a pressure that is less than a minimum pressure condition experienced in the pharyngeal conduit during a respiration cycle.

3. An apparatus according to claim 1, wherein the chamber is sized and configured to be worn about a neck.

4. A method of brace or fixate tissue in targeted pharyngeal structures and/or individual anatomic components within the pharyngeal conduit comprising the steps of providing an apparatus as defined in claim 1, and locating the apparatus outside the pharyngeal conduit.

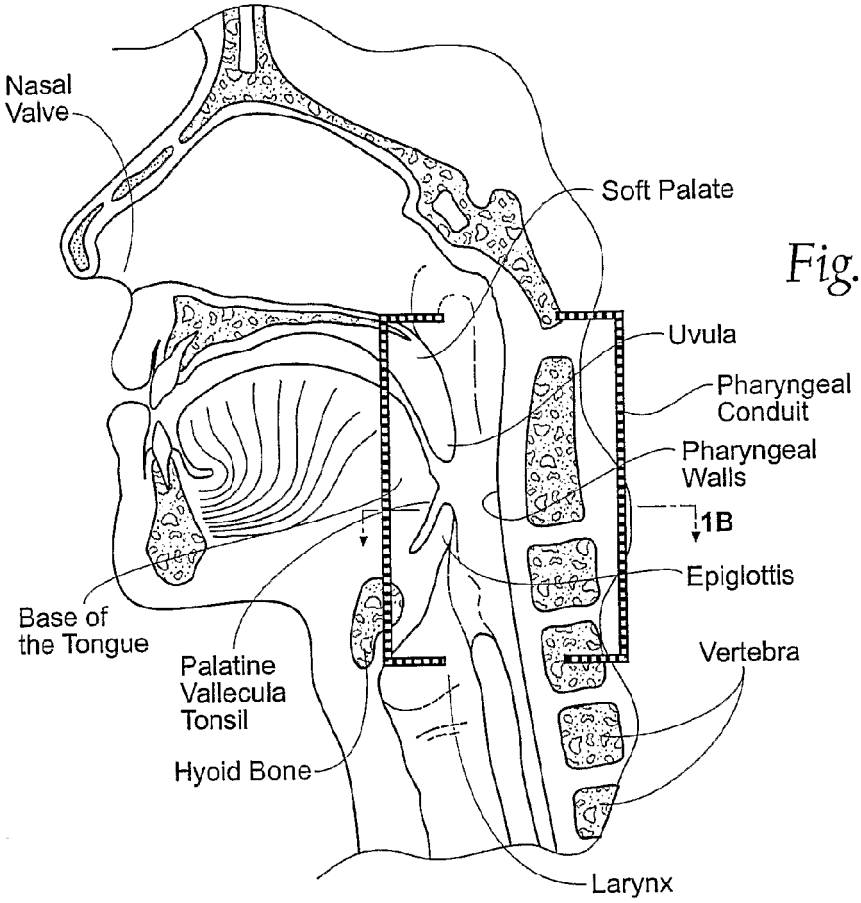
Nasal Valve
Soft Palate
Uvula
Pharyngeal Conduit
Pharyngeal Walls
1B
Epiglottis
Base of the Tongue
Palatine Vallecula Tonsil
Vertebra
Hyoid Bone
Larynx

Fig. 1A

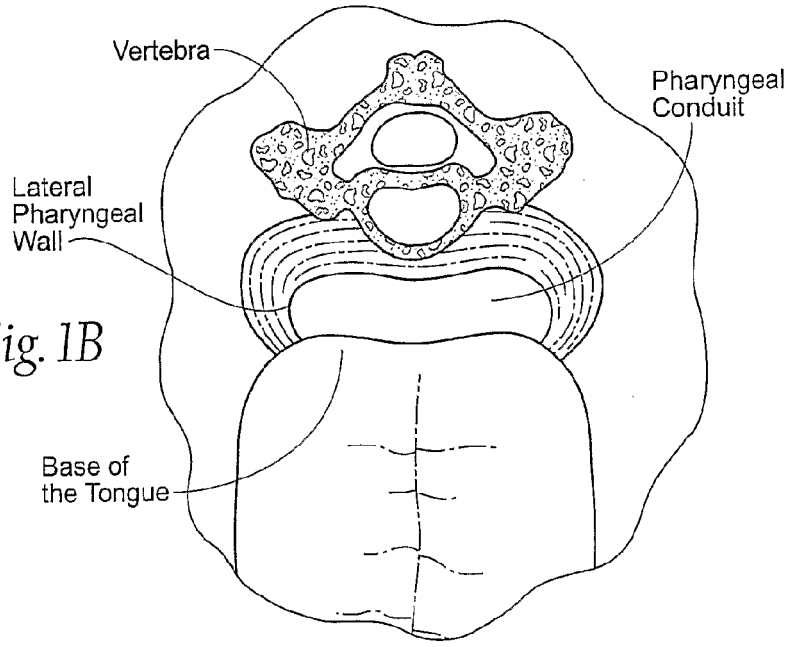
Vertebra
Pharyngeal Conduit
Lateral Pharyngeal Wall
Base of the Tongue

Fig. 1B

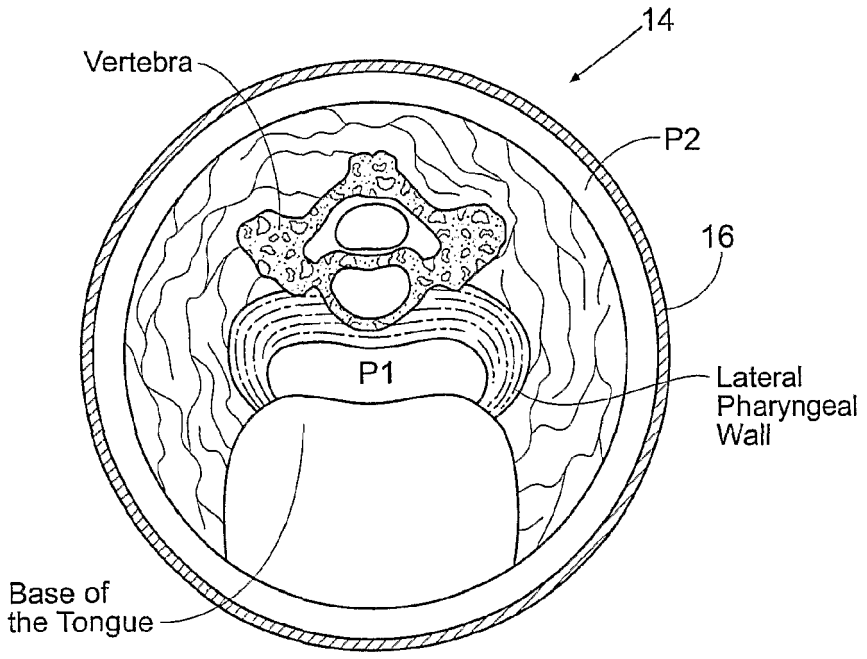
14
Vertebra
P2
16
P1
Lateral
Pharyngeal
Wall
Base of
the Tongue

Fig. 2

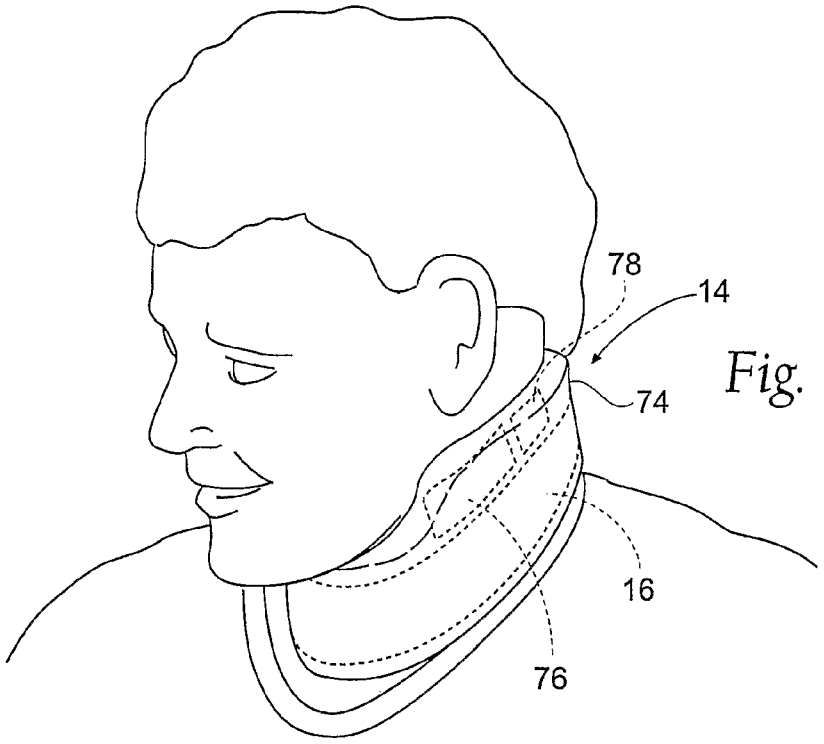
78
14
74
16
76

Fig. 3A

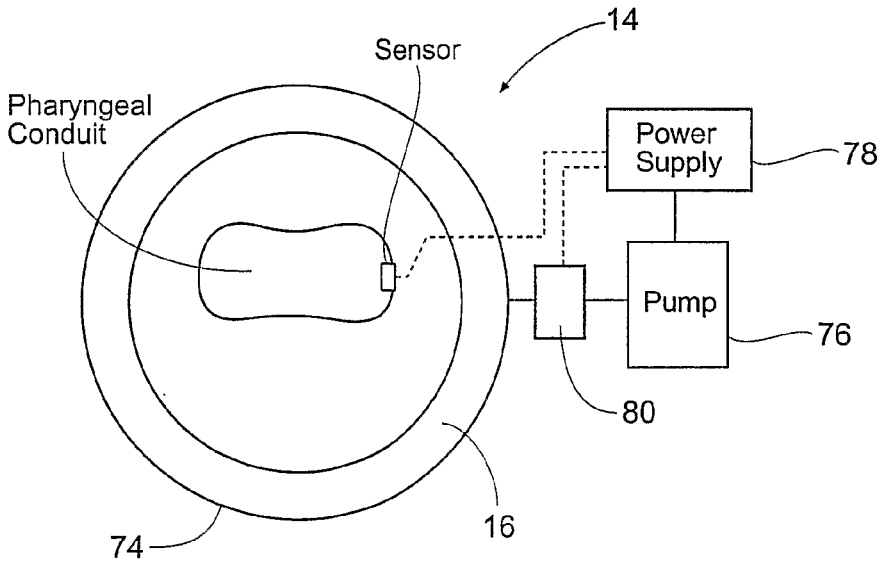
14
Sensor
Pharyngeal
Conduit
Power
Supply
78
Pump
76
80
74
16

Fig. 3B

REFERENCES CITED IN THE DESCRIPTION

This list of references cited by the applicant is for the reader's convenience only. It does not form part of the European patent document. Even though great care has been taken in compiling the references, errors or omissions cannot be excluded and the EPO disclaims all liability in this regard.

Patent documents cited in the description

- US 10656861 B **[0001]**
- US 10236455 B **[0001]**
- US 60441639 B **[0001]**
- US 60456164 B **[0001]**

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- **SCHWAB RJ ; GOLDBERG AN.** Upper Airway Assessment: Radiographic and other Imaging Techniques. *Otolaryngol Clin North Am,* 1998, vol. 31, 931-968 **[0012]**
- **ISONO S. ; REMMERS J ; TANAKA A ; SHO Y ; SATO J ; NISHINO T.** Anatomy of Pharynx in Patients with Obstructive Sleep Apnea and in Normal Subjects. *J Appl Physiol,* 1997, vol. 82, 1319-1326 **[0013]**
- **SHELLOCK FG ; SCHATZ CJ ; JULIEN P ; SILVERMAN JM ; STEINBERG F ; FOO TKF ; HOPP ML ; WESTBROOK PR.** Occlusion and Narrowing of the Pharyngal Airway in Obstructive Sleep Apnea: Evaluation by Ultrafast Spoiled GRASS MR Imaging. *Am J of Roentgenology,* 1992, vol. 158, 1019-1024 **[0014]**